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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Cooper & Dunham 1185 Avenue of the Americas New York, NY 10036				
EXAMINER MEHTA, ASHWIN D				
ART UNIT		PAPER NUMBER		
1638				

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,821

Applicant(s)

SELA ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-43 is/are pending in the application.
- 4a) Of the above claim(s) 8,10,12,31,32,35,36 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11,13-17,20-24,26-30,33,34,37,38 and 40-43 is/are rejected.
- 7) ☒ Claim(s) 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9202004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 2, 5, 16, 21, and 29 are withdrawn, in light of the claim amendments.
3. The rejection of claims 1-7, 9, 11, 13-19, 21, 25, and 27-30 under 35 U.S.C. 112, 2nd paragraph, are withdrawn in light of the claim amendments.

Election/Restrictions

4. Applicants continue to traverse the withdrawal of non-elected claims 8, 10, 12, 31, and 32, in the paper filed September 17, 2004. Applicants argue that it would not be a burden to examine these claims because they are related and not independent (response, page 22, 2nd full paragraph). However, the products and methods of the elected claims have the special technical feature of being drawn to use in plant cells, wherein a known gene is being silenced, which is not shared with the products and methods of the non-elected claims. The restriction requirement of Groups II-VIII and X, claims 8, 10, 12, 31, 32 is still deemed proper and remains FINAL. Applicants are reminded to remove non-elected subject matter from the elected claims. New claims 35, 36, and 39 are also withdrawn from consideration, as they are drawn to non-elected Group II.

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NOTE: In the claims amendments submitted September 17, 2004, claims 14 and 20 were incorrectly identified as "withdrawn." Claims 14 and 20 are not withdrawn.

Claim Objections

5. Claim 17 remains and claims 18-19 are objected to, for the reasons of record stated in the Office action mailed March 18, 2004. Applicants traverse the objection in the paper filed September 17, 2004. Applicants' arguments have been fully considered but were not found fully persuasive.

Claim 17 was objected to for failing to further limit the subject matter of a previous claim. Applicants argue that the claim amendments address the objection (response, page 25, 1st full paragraph). However, the amended claim only indicates that pT7 is the promoter region of bacteriophage T7 and is capable of initiating transcription. As stated in the previous Office action, the specification defines pT7 as being from bacteriophage T7. Therefore this recitation does not limit claim 1 or 2.

Claims 18 and 19 are objected to for depending from a rejected base claim.

Claim Rejections - 35 USC § 112

6. Claims 20, 22-24, and 26 remain and claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed March 18, 2004. Applicants traverse the rejection in the paper filed

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September 17, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

In the previous Office action, claims 1, 2, 20, 21, 27, and 28, and those dependent thereon, were rejected because the recitation, "corresponding to the T7 RNA polymerase gene" was found indefinite. Applicants argue that the claim amendments address the language objected to by the Examiner (response, paragraph bridging pages 30-31). However, claim 20 has not been amended.

Further, in claim 26: the claim is indefinite because it depends from cancelled claim 25.

In claim 40: the recitation, "or" in line 12 renders the claim indefinite. The recitation indicates that one or more steps are replaced by another step. However, it is unclear what those steps are. Does step c replace step b? However, step e indicates that the construct obtained in step b is always required. Alternatively, the recitation may indicate that text has been left out of step b. The metes and bounds of the claim are unclear.

In claim 42: the recitation, "and" in line 10 renders the claim indefinite. The recitation indicates that plant cells are transformed with the constructs of parts a) i) and a) ii). However, the claim subsequently indicates in part b) that cells are selected that can have just one of the constructs. It is unclear whether the cells made in part a) must have both the first and second constructs, or just one of them. The metes and bounds of the claim are unclear.

7. Claims 20 and 22-24 remain and claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed March 18, 2004. Applicants traverse the rejection in the paper filed September 17, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

Applicants argue that the cancellation of claim 25 and the amendments to claims 1, 2, 16, 20, 21, 27, and 28 satisfy the written description requirement (response, page 35, 2nd full paragraph to the paragraph bridging pages 35-36). The amendments overcome the rejection for claims 1-7, 9, 11, 13-19, 21, 25, and 27-30. However, claim 20 has not been amended.

8. Claims 6, 11, 20, 22-24, 30 remain and claims 26, 34, 38, and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression silencing system comprising a nucleotide sequence encoding the T7 RNA polymerase, and pT7, does not reasonably provide enablement for functional equivalents or fragments of nucleotide sequences encoding T7 RNA polymerase, pT7, and the NOS terminator; the expression silencing system wherein the target sequence is a non-coding sequence in the plant genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed March 18, 2004. Applicants traverse the rejection in the paper filed September 17, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

Regarding the issue concerning lack of enablement of functional equivalents or fragments of nucleotide sequences encoding the T7 RNA polymerase, pT7, or NOS terminator, Applicants

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argue that the claim amendments to claims 1, 2, 16, 20, 27, and 28 have been amended such that they no longer recite "functional equivalent or fragment thereof." However, claim 20 has not been amended.

Applicants argue that Example 5 of the specification describes the use of a non-coding sequence, the TMV translation enhancer element, to reduce virus-titer in transformed plants (response, page 39, 1st full paragraph and the paragraph bridging pages 39-40). It is noted, however, that silencing of target genes of plant pathogens is not part of the elected invention. It is also acknowledged that non-coding, transcribed but non-translated sequences may be targets in PTGS. However, claims 6, 23, 30, and new claims 34, 38, and 41 only recite, "a non-coding nucleic acid sequence", which encompasses non-transcribed sequences. It is suggested that the term, --transcribed-- be inserted in this recitation in these claims before the term, "non-coding".

Claim Rejections - 35 USC § 102

9. Claims 1-7, 13-15, and 17 remain and claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Lassner et al., for the reasons of record stated in the Office action mailed March 18, 2004. Applicants traverse the rejection in the paper filed September 17, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

Applicants argue that Lassner et al. describe the use of a single construct to demonstrate T7 RNA polymerase activity in vitro, and that it is not clear that transcription and translation would occur in vivo in plant cells. Applicants argue that the conclusion can be reached from the reference that a nucleotide sequence regulated by the T7 promoter should be over-expressed in cells already expressing T7 RNA polymerase. Applicants argue that Lassner et al. never mention

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the possibility of interference of endogenous promoters and genes by the expressed nucleotide sequence. Applicant argues that the instant invention comprises a double construct, not a single construct as in Lassner et al., and the use of the constructs in vivo in plant cells to induce gene silencing of endogenous and exogenous genes, not for overexpression as in Lassner et al.

(response, page 45, last paragraph to page 47, 3rd full paragraph). However, Lassner et al. do use two constructs, not one. Lassner et al. teach that T7 RNA polymerase enzyme activity was assayed by incubation with a DNA template containing a T7 promoter, and that the polymerase directed RNA synthesis (paragraph bridging pages 231-232). Therefore, Lassner et al. do teach a second construct as encompassed by the instant claims. That Lassner et al. use the constructs to achieve overexpression of genes is not germane to the question of anticipation. See *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The prior art was held to anticipate the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). See also *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Claimed composition was anticipated by prior art reference that inherently met claim limitation of "sufficient aeration" even though reference taught away from air entrapment or purposeful aeration.). Further, the discovery of a previously unappreciated property of a prior art composition does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property that is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195

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USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

10. Claims 1-7, 9, 13-17, 20-24, and 27-30 remain and claims 26, 33, 34, 37, 38, 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lassner et al. in combination with Blokland et al. (Plant J., 1994, Vol. 6, pages 861-877), and Palauqui et al. (EMBO J., 1997, vol. 16, pages 4738-4745), for the reasons of record stated in the Office action mailed March 18, 2004. Applicants traverse the rejection in the paper filed September 17, 2004. Applicants' arguments were fully considered but were not found fully persuasive.

Applicants argue that a *prima facie* case of obviousness has not been met, and submit a declaration under 37 C.F.R. 1.132, signed by co-inventor Dr. Ilan Sela, in support. The declaration states that the T7 silencing system differs from other silencing systems in that no siRNA could be detected, the silencing signal was not transduced across grafts, and the viral silencing suppressor Hc-Pro could not overcome the silencing effect. The declaration states that the T7 silencing system activity was confined to the nucleus, as silenced genes were methylated and pertinent siRNAs were detected in nuclear extracts, and dicer activity was enhanced (response, pages 50-51; declaration, item 21). However, these differences are not described in the specification as filed, nor are they encompassed by the claims. Further, the information in the declaration regarding the inability of the silencing signal to transduce across grafts (also discussed in items 27-30) directly contradicts the instant specification. Example 4 of the specification teaches that in 3 of 6 plants tested, the silencing signal did transduce across grafts. Page 4 of the specification states that "the invention relates to a method for producing a

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transgenic plant carrying a substantially silenced target sequence by grafting a plant, or parts thereof, carrying and expressing said silent target sequence on a transgenic plant obtained by the process of the invention.” Further, it is noted original claim 25 required grafting, and this claim was only cancelled in Applicants’ most recent response.

The declaration also points out supposed deficiencies of Blokland et al. (items 22-25). However, Applicants are arguing against the reference alone, not in combination with the other reference. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The declaration also states that another unique characteristic of the T7 silencing system is the capacity of using only a short homology fragment, around 70 nucleotides (item 26). However, the claims are not limited to using only such fragments.

Summary

11. Claims 18 and 19 are objected to, claims 1-7, 9, 11, 13-17, 20-24, 26-30, 33, 34, 37, 38, 40-43 are rejected, and non-elected claims 8, 10, 12, 31, 32, 35, 36, and 39 are withdrawn from consideration.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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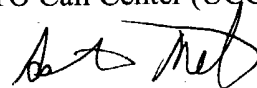
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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November 17, 2004



Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638